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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,613	10/26/2001	Jason C. H. Shih	4171-102 CIP	4213
23448	7590	06/30/2004	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329 RESEARCH TRIANGLE PARK, NC 27709			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,613	H. SHIH, JASON C.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61, 63-65, 68, 69, 71, 73-80 and 82 is/are pending in the application.
- 4a) Of the above claim(s) 1-38, 68, 69 and 75-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-61, 63-65, 71, 73, 74, 80 and 82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1-4-2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Currently, claims 1-61, 63-65, 68, 69, 71, 73-80, and 82 are pending in the application. In the prior action, mailed on December 16, 2003, claims 39-65, 71-74, and 80-83 were rejected; and claims 1-38, 66-70, and 75-79 were withdrawn as being drawn to a nonelected inventions. In the Response filed on April 16, 2004, the Applicant amended claims 39, 51-61, 64-65, 71, 80, and 82; and cancelled claims 62, 66, 67, 70, 72, 81, and 83.

Claims 39-61, 63-65, 71, 73, 74, 80, and 82 are under consideration to the extent that they read on the elected inventions.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on January 5, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

3. It is noted that the following references are listed in the above IDS' are in a foreign language accompanied by an English abstract. Due to this, the references have been examined only to the extent of the disclosure in the abstract.

WO 00/58344 (reference AK of the January 2002 IDS)

WO 01/09287 (reference AP of the January 2002 IDS)

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4. In the prior action, it was noted that four references in the January 2002 IDS had not been considered because they were submitted only as foreign language documents, with no English translation, abstract, or explanation of their relevance. These documents were as follows.

EP 0 667 352

EP 0 530 173

JP 11049611

JP 11032795

The Applicant has submitted English abstracts of these references with the Response, but has not cited them in a proper IDS. Although, for the purpose of expediting prosecution in the present application these references have been made of record in the attached form PTO-892; it is noted that these English abstracts have not been properly submitted to the Office for consideration. For future purposes, Applicant's attention is drawn to the following: MPEP § 609, subsections III (A)(1) (explaining requirement for listing of references), III (A)(3) (explaining requirement for explanation of relevance of foreign language documents), and III(C)(1) (stating that the determination as to whether an IDS meets the requirements of 37 CFR 1.97 and 1.98 is made at the time of the filing of the IDS).

Specification

5. **(New Objection)** The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: While there is support in the originally filed claims for the limitations of claims 52, 57, 58, 56, 59, and 71 there is no antecedent basis for the claimed temperature ranges of these claims in the specification. It is suggested that the Applicant insert

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such support into the specification into, for example, the first full paragraph on page 6 of the specification. Appropriate correction is required.

With respect to the limitations of claims 56, 59, and 71, the Applicant is cautioned against the insertion of New Matter into the application. See rejection of these three claims for New Matter under 35 U.S.C. 112, first paragraph below.

Claim Objections

6. **(Prior Objection- Maintained in part)** Claims 51-61, and 72 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the amendment of claims 51-59, 61, and 72, the objection is withdrawn s to these claims.

However, claim 60 reads on the system of claim 39 wherein the second temperature is in “a range from *about 40° C* to about 75° C.” The italicized phrase, about 40° C (which may allow for, e.g., 39 ° C), is broader than, and may fall outside, the requirements of claim 39, which require the temperature to be at least 40° C. The objection is therefore maintained against this claim.

As noted in the prior action, because the independent claims are drawn to compositions of matter, the identified claims are interpreted as product claims indicating the intended use of the claimed product. See, MPEP § 2114.01.

7. **(Prior Objection- Withdrawn)** Claims 64 and 65 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter

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of a previous claim. In view of the amendment of claim 64 such that it is now in independent form, the objection is withdrawn.

8. **(New Objection)** Claims 39-61, 63-65, 71, 73, 74, 80, and 82 are objected to because of the following informalities: these claims read on systems for the treatment of articles that may be infected with prion proteins. However, the systems are described in the claims as comprising the articles to be worked on by the apparatus. Because the articles so infected are to be treated by the system, it is inappropriate to include the articles in the claimed system as they are not deemed to impart patentability to the system. . Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. **(Prior Rejection-Maintained)** Claims 39-41, 44-53, and 56-62, were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed products that are capable of reducing the presence of prion protein on an article by heating it with a heating means to a temperature range of 100° to about 150° C and then exposing it to a proteolytic enzyme, does not reasonably provide enablement for the claimed system wherein the system is capable of disinfecting the instruments at temperatures of less than 100°C and exposure to any proteolytic enzyme. The claims have been amended such that they are now limited to

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embodiments wherein the enzyme is one of a keratinase, or a subtilisin. The rejection is maintained against claims 39-52, 56-61, 64, and 65.

Because claim 53 has been amended to indicate a minimum temperature of 60° C, and because of the Applicant has demonstrated the efficacy of both keratinase and subtilisins at temperatures of at least 50°C, the rejection is withdrawn as to this claim.

The Applicant traverses the rejection on the grounds that the Applicant has established that the claimed methods is effective wherein the first temperature is one of 50°C , 80°C, 90°C, 100°C, and 115°C and the enzyme is one of a purified keratinase, a subtilisin, or a crude keratinase. The Applicant argues that, in view of these teachings, the applicant is enabled for temperatures of lower than 100°C using the indicated enzymes. This argument is persuasive in part. However, the scope of the Applicant's showings does not correspond to the scope of the claimed inventions. Thus, while the Applicant appears to be enabled to methods wherein the first temperature is at least 50°C, the Applicant is not enabled for embodiments wherein the temperature is any temperature "not exceeding about 150°C," or for temperatures of less than 50°C. The rejection is therefore maintained against the claims reading on such embodiments.

11. **(Prior Rejection-Maintained)** Claims 64 and 65 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for systems comprising a complete keratinase or *B. licheniformis* PWD-1 enzyme, does not reasonably provide enablement for systems comprising only enzymatically active fragments of these enzymes. The Applicant traverses this rejection by asserting that the Applicant need not teach what is well known in the art, and that those in the art may use the well-known technique of terminal truncation to generate

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all possible fragments of the enzyme, and thereby determine which fragments maintain the protease activity. This rejection is not found persuasive because the Applicant has neither demonstrated that those in the art are aware of the active fragments of the indicated enzyme, nor has the Applicant provided teachings commensurate with the scope of the claims. Rather, the Applicant is attempting to claim the use of fragments of the indicated enzyme, but is leaving it to those in the art to determine for themselves which fragments may be used in the claimed invention. For the reasons indicated in the prior action (i.e. the breadth of the claims, the lack of guidance, and the unpredictability in the art), and because the Applicant has not provided any evidence to demonstrate that those in the art would have been aware of which fragments may be used in the claimed invention at the time the application was filed, the rejection is maintained.

12. **(Prior Rejection- Withdrawn)** Claims 81 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. These claims have been cancelled from the application. The rejection is therefore withdrawn.

13. **(New Rejection-Necessitated by Amendment)** Claims 56, 59, 71, 73, and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. There does not appear to be written description support for the temperature range limitation of claim 56, or the temperature range limitations with respect to the second

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temperature provide in claims 59, and 71. The Applicant is requested to either point out where, in the originally filed application, support for these limitations may be found, or to cancel the New Matter from the claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **(Prior Rejection- Maintained)** Claims 39-64, and 71-73 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of the World Health Organization (WHO) document identified as reference BT in the March 2003 IDS in view of Huth et al. (U.S. Patent 6,448,062), Vlass et al. (U.S. Patent 6,210,639), and Potgeiter et al. (U.S. H1,818), and further in view of the teachings of Bolton (supra) and Oesch et al. (Biochemistry 33: 5926-31). The rejection is withdrawn as to claims 62 and 72, which have been cancelled from the application. The rejection is maintained over claims 39-61, 63, 64, 71, and 73.

The rejected claims read on systems for the disinfection of articles comprising the articles to be disinfected, means for heating the articles, proteolytic enzymes, and means for exposing the articles to the enzymes. Among the enzymes included in the system are keratinase enzymes. It is noted that, based on the recitation of structural elements, and the election of the group describing a kit in the paper filed on September 23, 2003, the claimed "systems" are being treated the same

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as kits comprising such elements. The application has not provided any specific means for the heating the articles, or for exposing the articles to the enzymes. The claims thus read on systems comprising any such means.

The Applicant appears to have provided two arguments in traversal of the rejection. First, the Applicant argues that the prior art does not teach the functional elements of the claimed invention. Second, the Applicant also appears to argue that the references do not teach the combination of the means for heating with the proteolytic enzymes.

The Applicant has traversed the rejection on the grounds that the art does not teach the recited processes of using the claimed system. It is first noted that the rejected claims are apparatus claims, and are not directed to a particular method. In the examination of an apparatus, such as the system being claimed, section 2114 of the MPEP states that the claimed apparatus "must be distinguished from the prior art in terms of structure rather than function." The MPEP also states that a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" so long as the prior art apparatus teaches all the structural limitations of the claim. MPEP § 2114 (citing, Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)). See also, MPEP § 2115 (quoting the court of In re Casey, 152 USPQ 235 (CCPA 1967), stating "the manner or method in which [a machine for the production of an article] is to be utilized is not germane to the issue of patentability of the machine itself"). In the present case, the Applicant has not argued that the combination of elements disclosed by the prior art would be incapable of performing the claimed method. Rather, the Applicant has asserted that the art does not teach the new method of using

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the prior art combination of apparatus. Because the Applicant has not structurally distinguished the claimed invention from the prior art, the argument is not found persuasive.

The second argument appears to be an assertion that, because the prior art references do not teach the use of proteolytic enzymes at elevated temperatures, the references do not render the claimed invention obvious. However, the art does teach both the use of a means for heating the articles, and the exposure of the articles to such enzymes, for the sterilization of medical instruments. As was noted above, the claims are not directed to methods, but to an apparatus (or combination thereof), and the Applicant has not provided any evidence that the combination of enzymes and means for heating in the prior art differs structurally from the claimed system. In view of this, the Applicant's arguments that the art does not teach the preferred method of using the articles is not found persuasive because the Applicant has not demonstrated that the combination suggested by the art is capable of being used in the processes suggested by the claims. The rejection is therefore maintained.

16. **(Prior Rejection- Maintained)** Claims 65, 74, 80, and 82 were rejected under 35 U.S.C. 103(a) as being unpatentable over the WHO reference, Vlass, Huth, Potgeiter, Bolton, and Oesch as applied to claims 39-64, and 71-73 above, and further in view of Shih et al. (U.S. Patent 5,171,682). These claims read on the system described above, wherein the keratinase enzyme is the *B. licheniformis* PWD-1 keratinase. The Applicant traversed this rejection on the same basis as was addressed with respect to the rejection of claims 39-64, and 71-73 above. The rejection is maintained for those reasons, and for the reasons of record.

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17. **(Prior Rejection- Withdrawn)** Claims 81 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over the WHO reference, Vlass, Huth, Potgeiter, Bolton, Oesch and Shih as applied against claims 39-65, 71-74, 80, and 82 above, further in view of any of Darbord (supra), Taylor et al., (J Gen Virol 77: 3161-64), or Belhumeur et al. (WO 00/65344). In view of the cancellation of these claims, the rejection is withdrawn.

Conclusion

18. No claims are allowed.

19. The following prior art references, made of record in the IDS of Jan 5, 2004, are considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

The Disch patents cited in the IDS are considered relevant in that they duplicate in part the teachings of the reference in the 103 rejections above. In particular, the references teach the combination of a means for heating, a means for exposing, and a proteolytic enzyme for the cleansing of medical equipment, and suggest the use of an enzyme from *B licheniformis*.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

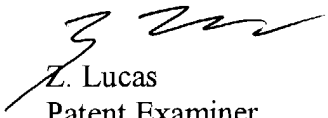
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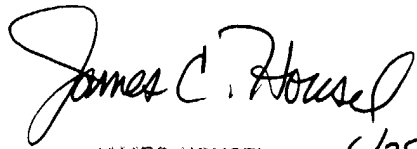
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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6/28/04